

June 21, 2018

Ethylene Oxide (EtO)

Background (background of EtO issue submitted by Alice-do we still need-should we emit first paragraph))

EtO is listed as a hazardous air pollutant in the 1990 Clean Air Act Amendments. In December 2016 the U.S. Environmental Protection Agency (EPA) updated its EtO inhalation cancer risk estimate. The prior estimate was based on experimental animal results, while the 2016 estimate relies more on human study data. Formerly categorized as a probable carcinogen, the 2016 update concluded that EtO is carcinogenic to humans, in agreement with the International Agency for Research on Cancer (2012). Human studies show that sufficient exposure to EtO may result in lymphoid cancer and breast cancer in females.

Depending on exposure assumptions, the updated EtO inhalation cancer risk estimate is about 30-60 times higher than prior values. This means EPA now believes EtO is considerably more potent than previously thought for inducing human cancer. Evidence considered in the 2016 update indicates that children under 16 years of age have greater susceptibility to EtO's inhalation cancer risk. The updated EtO cancer potency information supports the need to reduce EtO air emissions.

R3 EtO PA facilities with risks greater than 100 in a million:

R3 EtO facilities with risks greater than 100 in a million (see Powerpoint attachment)

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B Braun Allentown, PA Major source—3.3 EtO emissions

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R3 EtO PA facilities with risks less than 100 in a million:

Oakland Veterans Hospital, Pittsburg, PA Minor source—0.002 EtO emissions Communication Status re: 2014 NATA

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• We have discussed with all our S/Ls about facilities with greater than 100 in a million inhalation risk based on draft 2014 NATA emission estimates. Our S/Ls have checked their data and have confirmed their veracity. The current facility estimates will be finalized in by end of June/early July.

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• The EtO risk information are still internal to EPA. It has not been publicly released.

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• To get ready for public release of 2014 NATA (late August 2018)

○ OAQPS will be developing the communication plan for 2014 NATA that will be shared with S/Ls prior to release.

○ We expect that our typical coke oven facilities will again top the list for risk, but now, EtO will most likely surpass those risks.

○ We have internally discussed with air enforcement and air permitting about any recent inspections or permit reviews for EtO facilities.

~~○ We began discussions with DNREC on the Croda facility in New Castle county for EtO. DNREC has been working with the facility to gain additional controls through their permit. We discussed possibly conducting air sampling (Method TO-15) before and after any new controls...it would establish a baseline for which any emission reductions could be measured, as this was DNREC's concern.~~

~~○ We expect to hold similar discussions with WV and PA for their high risk EtO facilities.~~

CAA Compliance Summary – compiled from EPA's ECHO Database.

- B. Braun – Allentown, PA; PA; CAA Major Source. Last CAA On-site inspection from PADEP 3/14/2018, last CAA Off-Site Inspection 6/12/18. EPA ECHO Database does not show any formal enforcement actions within the last five years by either PADEP or EPA. Commercial Sterilizer.
- ~~○ Croda – New Castle, DE; CAA Area Source. Last CAA On-site inspection from DNREC 2/21/17, last CAA Off-site inspection 3/23/18. DNREC issued CAA Notices of Violation 4/25/14 and 9/14/15. EPA last CAA inspection 5/17-19/2010. Chemical Plant.~~
- ~~○ Union Carbide – South Charleston, WV; CAA Major Source. Last CAA On-Site Inspection from WVDEP 8/17/16. Last EPA CAA inspection 7/27-30/2009. EPA ECHO Database does not show any formal enforcement actions within the last five years by either WVDEP or EPA. Chemical Plant.~~
- ~~○ Union Carbide Institute, WV; CAA Major Source. Last CAA On-Site Inspection from WVDEP 4/26/18, last Off-site PCE 4/19/18. Last EPA CAA Inspection 11/1-4/2010. WVDEP CAA Administrative Formal Actions – 1/14/17, 10/16/16. Site is also listed as Bayer Crop Science Institute. EPA conducted inspection 4/5-7/2011 and issued an Administrative Order 11/11/2013. Chemical Plant.~~

~~Additional Pennsylvania Facility –~~

- Oakland VA Medical Center – Pittsburgh, PA – CAA Synthetic Minor Source. Last CAA On-Site Inspection from PADEP 8/25/2016, last CAA Off-site inspection 9/11/14. ECHO Database does not show any formal enforcement actions within the last five years by either PADEP or EPA. Hospital/ Sterilizer.